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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,379	07/01/2003	Oliver Hobert	5199-92	7972

7590 01/07/2005

Brown Raysman Millstein Felder & Steiner LLP
163 Madison Avenue
P.O. Box 1989
Morristown, NJ 07962-1989

EXAMINER

GAMETT, DANIEL C

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,379

Applicant(s)

HOBERT, OLIVER

Examiner

Daniel C Gamett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to nucleic acids encoding *C. elegans* chloride intracellular channel protein, recombinant vectors comprising said nucleic acid, cells comprising said vectors, and methods of making said protein, classified in class 536, subclass 23.5.
 - II. Claims 11-19, drawn to antibodies that specifically recognize *C. elegans* chloride intracellular channel protein, classified in class 530, subclass 387.9.
 - III. Claims 20-22, drawn to a method of identifying an agent that inhibits CLIC activity, classified in class 435, subclass 7.1.
 - IV. Claims 23-26, drawn to a method of identifying an agent that inhibits CLIC expression or function in wild-type *C. elegans* embryos or cells, classified in class 435, subclass 4.
 - V. Claims 27-30, drawn to a method of identifying an agent that inhibits CLIC expression, classified in class 435, subclass 6.
 - VI. Claims 31-33, drawn to a method of determining if a CLIC gene is involved in tubulogenesis, classified in class 435, subclass 455.
 - VII. Claims 34-39, drawn to drawn to a method of identifying an agent that inhibits CLIC expression or function in *exc-4* mutant *C. elegans* embryos or cells, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and each of V, VI, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid, vectors, and transformed cell products of Invention I can be used for antisense inhibition of CLIC expression or to raise antibodies to CLIC protein which are materially different processes than detection of CLIC expression (Group V), rescuing the excretory phenotype of *exc-4* mutant cells (Group VI) or detecting an agent that inhibits CLIC expression or function (Group VII).
3. Inventions I and both III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids, vectors, and transformed cells of Group I are not used in the methods of Inventions III or IV. The inventions of Groups I, III, and IV have a separate status in the art as shown by their different classifications. As such it would be burdensome to search the Inventions I and either III or IV together.
4. Inventions I and II are unrelated. Invention II is an antibody molecule, which is chemically distinct from the nucleic acids, vectors, and transformed cells of Group I. The inventions of

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Groups II and I have a separate status in the art as shown by their different classifications and each would require non-coextensive searching of separate databases. As such it would be burdensome to search the Inventions II and I and together.

5. Inventions II and each of III-VII are unrelated. Inventions III-VII are methods that neither use nor rely upon the antibody molecule of Invention II. The inventions of Groups II and each of the other Groups have a separate status in the art as shown by their different classifications. As such it would be burdensome to search the Inventions II and any of III-VIII together.
6. Inventions III, IV, V, VI, and VII are unrelated each to the other. Invention III is an assay which is narrowly focused on the activity of a single type of chloride channel. Invention V measures *exc-4* gene expression. Invention IV encompasses effects on excretory cell phenotype as well as effects of a test agent that may act directly on the CLIC protein or at the level of gene expression. Invention VI is an assay for phenotypic rescue of mutant *C. elegans* by recombinant gene expression. Invention VII encompasses phenotypic rescue of mutant *C. elegans* as well as screening of agents for a broad scope of effects that includes effects on excretory cell phenotype, CLIC gene expression and direct effects on the CLIC protein. Thus these Inventions have different modes of operation, different functions, different effects, and each requires a search that would be non-coextensive with any other Invention. The inventions of Groups III –VII each have a separate status in the art a shown by their different classifications. As such it would be burdensome to search the any two of Inventions III-VII together.

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7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and separate search requirements, restriction for examination purposes as indicated is proper.
8. This application contains claims directed to the following patentably distinct species of the claimed invention: The agent of interest:

- a.* A peptide
- b.* A nucleic acid
- c.* An antibody
- d.* A drug
- e.* A compound
- f.* A molecule
- g.* A dominant-negative antagonist
- h.* Indanyloxyacetic acid-94
- i.* N-ethylmaleimide
- j.* glutathione

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from (*a-j*) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 20, 23, 27, and 34 are generic.

8. This application contains claims directed to the following patentably distinct species of the claimed invention: ONE human CLIC gene from the six CLIC genes listed in Claims 33 and 36.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from human CLIC gene 1-6 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 31 and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). **IF APPLICANT ELECTS GROUP III, IV, V, or VII**, one species from the agent of interest group (a-j) must be chosen to be considered fully responsive. **IF APPLICANT**

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ELECTS GROUP VI, or VII, one species of the CLIC gene group must be chosen to be considered fully responsive.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

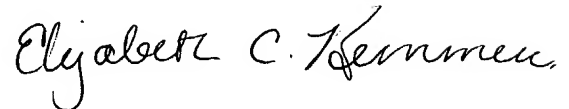
10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DCG
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4 January 2005

ELIZABETH KEMMERER
PRIMARY EXAMINER